Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor.distress syndrome.

Protocol summary

Summary

Objective: A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor. Design: Method: double blind randomized clinical trial. Setting and conduct: Eligible women will be randomly assigned in the two groups of A and B. In group A, two doses of 12 mg betamethasone with the interval of 12 hours and in group B, two doses of 12 mg betamethasone with the interval of 24 hours will be prescribed. Participants:The women with preterm labor. Inclusion criteria: singleton pregnancy and gestational age of 26-34 weeks. Exclusion criteria: known allergy for betamethazone; history of any known maternal systemic disorders like hypertension, diabetes, liver and cardiac disease, renal failure and neoplasia. Intervention: In group A, two doses of 12 mg betamethasone with the interval of 12 hours and in group B, two doses of 12 mg betamethasone with the interval of 24 hours will be prescribed. Main outcome measures: preterm neonates of the two groups will be compared according to respiratory distress syndrome, intra ventricular hemorrhage, retinopathy, necrotizing enter colitis, neonatal death, and NICU admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402072624N11**
Registration date: **2014-03-25, 1393/01/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-25, 1393/01/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor.distress syndrome.

Public title

Betamethasone administration in preterm labor.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy and gestational

age of 26-34 weeks. Exclusion criteria: known allergy for betamethazone; history of any known maternal systemic disorders like hypertension, diabetes, liver and cardiac disease, renal failure and neoplasia.

Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic comittee of Tehran University of Medical Sciences
Street address
Keshavarz Boulvard, Ghods Cross.
City
Tehran
Postal code
Approval date
2013-12-15, 1392/09/24
Ethics committee reference number
92/130/2123

Health conditions studied

1

Description of health condition studied
Preterm labor
ICD-10 code
o60
ICD-10 code description
Preterm labour and delivery

Primary outcomes

1

Description
Respiratory distress syndrome
Timepoint
After delivery
Method of measurement
sign and symptoms by pediatrician

Secondary outcomes

1

Description
intra ventricular hemorrhage
Timepoint
After birth up to discharge.
Method of measurement
Diagnosis by pediatrician.

2

Description
retinopathy
Timepoint
After birth up to discharge.
Method of measurement
Diagnosis by ophtalmologist

3

Description
necrotizing enter colitis
Timepoint
After birth up to discharge.
Method of measurement
Diagnosis by pediatrician.

4

Description
neonatal death
Timepoint
After birth up to discharge.
Method of measurement
neonatal sheet

5

Description
NICU admission
Timepoint
After birth up to discharge
Method of measurement
neonatal sheet

Intervention groups

1

Description
prescription of two doses of 12 milligram betamethasone with 24 hours interval.
Category
Treatment - Drugs

2

Description
prescription of two doses of 12 milligram betamethasone with 12 hours interval.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Teaching Hospital
Full name of responsible person
Maryam Kashanian
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Molavi avenue, Molavi Cross.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Iran University of Medical Sciences.
Full name of responsible person
Dr. Motavallian
Street address
Hemmat High way, Chamran Cross.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research ,Iran University of Medical Sciences.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty